

Remarks

Claims 1 and 2 are pending in this case. New claims 3 and 4 have been added by this amendment. Support for new claims 3 and 4 can be found throughout the specification and particularly at pages 3 and 5. Claims 1 and 2 were rejected by this Office Action.

Claims 1 and 2 were rejected under 35 USC 102(a) in view of Jerussi because it was maintained that it is reasonable to assume that the 99.9% purity ODV compound of Jerussi was in crystalline form. Applicants respectfully maintain that a crystalline ODV base compound was not formed under the conditions taught by Jerussi and this rejection should be withdrawn.

First, as Applicants have previously asserted, the zwitterionic point for ODV base (i.e. about pH 9.5) is higher than the reaction condition of Jerussi (pH 6.8-6.9). ODV base would not be expected to crystallize in the reaction mixture where the zwitterionic point of ODV base is not reached.

Second, by comparing the NMR data for Applicants' ODV free base to that of Example 2 of Jerussi it is clear that the resultant compounds are different.

Applicant's free base NMR: N-dimethyl singlet 2.15; NCH₂ at 3.00 and 2.36.

Example 2 (Jerussi): N-dimethyl singlet 2.3; NCH₂ at 3.15 and 2.50.


Accordingly, Jerussi does not anticipate Claims 1-4 of the instant invention and this rejection should be withdrawn.

Claims 1 and 2 were rejected as being obvious over Jerussi and/or Husbands because it was maintained that one skilled in the art would have been motivated to make the crystalline form of ODV base in order to purify a well known pharmaceutical compound. Applicants respectfully traverse this rejection. To support an obviousness rejection there must be some motivation taught by Jerussi or Husbands. Applicants maintain that this motivation is simply lacking.

Jerussi does not teach or suggest making a crystalline form of ODV base. Jerussi teaches that the derivatives of venlafaxine are typically prepared as hydrochloride salts, and preferably as monohydrates. (See page 3, lines 27-30). Thus, one skilled in the art would be motivated to prepare HCl salt of ODV, rather than a crystalline ODV base.

Husbands does not cure the deficiencies of Jerussi. Husbands teaches conversion of non-crystalline ODV base to its fumarate salt. Husbands, like Jerussi does not provide the requisite motivation to prepare a crystalline ODV base. Accordingly, the teaching and motivation to prepare crystalline ODV base is lacking and this rejection should be withdrawn.

In view of the foregoing, Applicants maintain that Claims 1-4 are in condition ready for allowance and respectfully request an early and favorable Notice of Allowance.



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